

DANDRUFF- pyrithione zinc shampoo
Vi-Jon, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mountain Falls 253.001-253AB-AC-AD Dandruff Shampoo

Active ingredient

Pyrithione zinc 1%

Purpose

Anti-dandruff

Use

helps prevent recurrence of flaking and itching associated with dandruff

Warnings

For external use only

When using this product

do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

condition worsens or does not improve after regular use as directed

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well
- for maximum dandruff control, use every time you shampoo
- wet hair, massage onto scalp, rinse, repeat if desired
- for best results use at least twice a week or as directed by a doctor

Inactive ingredients

water, sodium lauryl sulfate, sodium laureth sulfate, glycol distearate, sodium chloride, zinc carbonate, sodium xylenesulfonate, amodimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, citric acid, methylchloroisothiazolinone, methylisothiazolinone, blue 1, red 33

Multiple benefit formula to help:

- Fight dry scalp
- Calm itch
- Relieve irritation
- Soothe and reduce redness
- Reduce oiliness
- Prevent flakes
- Leave hair healthy looking

*This product is not manufactured or distributed by Procter & Gamble, distributor of Head & Shoulders

Pyrithione Zinc Dandruff Shampoo + Conditioner Old Spice Men 2 in 1.
Manufactured by: Vi-Jon, Inc.
St. Louis, MO 63114
Questions or Comments? 1-888-593-0593
Made in the USA with US and foreign parts.

principal display panel

Mountain falls
*Compare to Head & Shoulders
Helps prevent flakes
+ conditioner
Leaves hair clean and managable
pH balanced formula
2 in 1 Dandruff Shampoo with pyrithione zinc
smooth spice
23.7 FL OZ (700 mL)

DANDRUFF			
pyrithione zinc shampoo			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-253
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)		PYRITHIONE ZINC	10 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
water (UNII: 059QF0KO0R)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			
GLYCOL DISTEARATE (UNII: 13W7MDN21W)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
ZINC CARBONATE (UNII: EQR32Y7H0M)			
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)			
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)			
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)			
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)			
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
D&C RED NO. 33 (UNII: 9DBA05BB0L)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-253-15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
2	NDC:11344-253-15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
3	NDC:11344-253-21	88 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
4	NDC:11344-253-35	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	05/31/2016	

Labeler - Vi-Jon, LLC (150931459)

Registrant - Vi-Jon, LLC (088520668)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11344-253)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11344-253)

Revised: 8/2021

Vi-Jon, LLC